Section 6: 510(k) Summary (21 CFR § 807.92(c))

DEC 2 1 2012

Submitter:	Glooko, Inc. 170A University Avenue Palo Alto, CA 94301
Contact:	Shilpa Mydur Regulatory Affairs Manager Phone: 650.521.0175 Email: shilpa@glooko.com
Date Summary Prepared:	14 December 2012
Device Trade Name:	Glooko Device System for the Glooko Logbook Application & Glooko Logbook Charts
Common Name:	Blood Glucose Meter and Data Management System
Classification Name:	System, Test, Blood Glucose, Over the Counter (21 CFR §862.1345) Calculator/data processing module for clinical use (21 CFR §862.2100)
Product Code:	NBW and JQP
Equivalent Devices:	GlucoFacts Express Data Management Software (K082486)

Device Description:

The Glooko device system for the Glooko Logbook Application includes the following:

- Glooko MeterSync Cable
- Glooko IR Adapter
- Glooko Logbook Application

Glooko MeterSync Cable

The Glooko MeterSync Cable downloads data from compatible, FDA-cleared, commercial blood glucose meters into an iOS device by connecting the two components. One end of the Glooko MeterSync Cable plugs directly into the 30-pin connector slot of the iOS device. The 3.5mm end of the Glooko MeterSync Cable plugs directly into most compatible meters to allow for the transfer of data. Some meters require an additional 3.5mm to 2.5mm adapter to allow for this

connectivity, while other meters transfer data through infrared, and thus require the use of the Glooko IR Adapter.

The Glooko MeterSync Cable is designed to attach to a variety of compatible, FDA-cleared, commercial blood glucose meters. The users simply connect the supported meters to their iOS device and transfer the blood glucose meter data into the Glooko Logbook Application.

Glooko IR Adapter

The Glooko IR Adapter is designed to transmit data via infrared from a variety of compatible, FDA-cleared, commercial blood glucose meters into the Glooko Logbook Application. The user connects the Glooko IR Adapter to the 3.5mm adapter end of the Glooko MeterSync Cable to transmit data from the compatible meters.

Glooko Logbook Application

This iOS Application logs the user's blood glucose values and meal tags that are downloaded from compatible blood glucose meters. The Glooko Logbook Application performs the following functions:

- *Syncs* with compatible meters
- Allows users to *annotate* readings with notes
- Provides multiple *view* options for the data
- *Shares* the collected data in multiple formats to anyone the user selects.

Glooko Logbook Charts

The Glooko™ Logbook Charts is a data management software tool designed to assist people with diabetes who self-manage their Blood Glucose (BG) readings. The Logbook Charts software is used in conjunction with the Glooko MeterSync Cable and the Glooko Logbook Application. The MeterSync Cable and the Glooko Logbook Application allow users to download BG readings from commercially available blood glucose meters to an iOS (iPhone Operating System) device. The Glooko Logbook Charts software tool enables the Glooko Logbook Application users to chart and graph their BG values from the Glooko Logbook Application. Glooko Logbook Charts is a spreadsheet program developed in Microsoft Excel and helps with quantitatively evaluating the BG data downloaded into the Glooko Logbook Application. Users can download the Glooko Logbook Charts sheet template from the Glooko website to generate and display reports on average BG values and BG trends. Several statistical parameters are calculated and the data is plotted as scattergrams relating blood glucose by time of day and by date. Glooko Logbook Charts specifically offers the following charts and table for view:

a. *BG readings By Time of Day*: provides an overview of glucose readings during the day.
b. *BG readings By Date*: provides an overview of glucose readings over a specified date range.
c. *BG readings Analysis By Time Of Day:* provides an overview of analyzed glucose readings during the day with high and low values, percentiles, mean and medians.
BG readings Summary Statistics: provides an overview of the analyzed glucose readings in table format.

Intended Use:

The Glooko device system for the Glooko Logbook Application and Glooko Logbook Charts is data management software intended for use in home and professional settings to aid individuals with diabetes and their health care professionals in review, analysis and evaluation of blood glucose readings to support an effective diabetes management program. The Glooko device system for the Glooko Logbook Application connects to compatible FDA cleared meters and allows users to transfer their blood glucose meter results to their iPhone operating system platform.

The Glooko device system for the Glooko Logbook Application and Glooko Logbook Charts are not intended to provide treatment decisions or to be used as a substitute for professional healthcare advice.

Summary of Testing:

The Glooko Logbook Application, MeterSync Cable and Charts software underwent verification and validation testing. A brief summary of the tests performed is described below. These studies demonstrated that the Glooko Device System performed according the specifications and the intended use.

Software Verification and Validation

- For Glooko Device system: The Glooko Device system (Glooko Logbook Application, Cable and Adapter) was validated pursuant to the moderate level of concern requirements. Design validation testing confirmed that the Glooko device performs according to the stated intended use. Device evaluation consisted of functional testing performed pursuant to Glooko's design verification protocol, which referenced FDA's guidance document for medical devices containing software. Such testing included Data Integrity Verification, Software Design/features Verification, and error handling testing. All test results fell within the pre-determined specification parameters.

- For Glooko Logbook Charts: The Glooko Logbook Charts software was validated pursuant to the moderate level of concern requirements. Design validation testing

confirmed that the Glooko device performs according to the stated intended use. Device evaluation consisted of functional testing performed pursuant to Glooko's design verification protocol which referenced FDA's guidance document for medical devices containing software. Such testing included Characterization of the Glooko Logbook charts spreadsheet, Data Integrity Verification, Software Design Verification, Microsoft Excel Version Testing and Glooko Logbook Version testing. All test results fell within the pre-determined specification parameters.

Usability Study:

- Glooko Device System: Glooko has conducted a usability performance validation study of the Glooko Logbook Application and MeterSync Cable (version 1.0.0) under an IRB approved protocol. This study was conducted in May 2011. Twenty patients with Type 1 or Type 2 diabetes participated in this study. The test goals for this study were to validate:
  - Accuracy of data download into the Glooko device System
  - Ability to share (transmit, download, save and email) and annotate data
  - Effectiveness of user manual
  - Ease of use of the Glooko MeterSync Cable and the Glooko Logbook Application

The Glooko Logbook Application is at version 1.5.0 at the time of this submission. Glooko has conducted a usability performance validation study with individuals for the first version of the Glooko Logbook Application v1.0.0. Additionally, Glooko has conducted usability / validation studies with individuals and / or healthcare professionals with subsequent versions of the application as part of Glooko's design control procedures. For the purpose of this 510(k), usability studies for Glooko Logbook Application v1.0.0, v1.4.0, and v1.5.0 will be discussed.

Studies from version 1.0.0 were chosen because it included the use of the Glooko MeterSync Cable and the Glooko Logbook Application. Version 1.4.0 included the use of Glooko IR adapter, MeterSync Cable and the Glooko Logbook Application. Version 1.5.0 is chosen because it is the latest version of the Glooko logbook Application and is also subject of this 510(k) submission. The basic operating principles have remained constant across all the versions of the Glooko logbook Application.

Together, the results from the testing of all the Glooko logbook Application versions have demonstrated the proper intended use for the Glooko device system for the Glooko Logbook Application.

- Glooko Logbook Charts: A usability performance validation study was conducted in May 2012 for the Logbook Charts software under an IRB approved protocol. Twenty patients with Type 1 or Type 2 diabetes and fifteen healthcare professionals participated in this study. The test goals for this study were to validate:
  - Effectiveness of the User Manual
  - Ability to transmit, download, save and email csv files
  - Ability to view and print the Logbook Chart graphs

The results from these two usability tests demonstrate that the product performs as intended in the hands of lay users and healthcare professionals. .

Statement of Equivalence:

The Glooko device is substantially equivalent to the predicate device with regards to its intended use and function. Both the subject and predicate devices are intended to download BG meter data to a secondary device. Additionally, the Logbook Chart software tool is similar to the GlucoFacts Express Data Management Software, which allows for the transfer of blood glucose values along with the time, date and certain data markers to a personal computer. Lastly, both the subject and predicate device are able to analyze BG data producing basic statistics and graphs / tables such as: Glucose trend results by date, Glucose results by time of day and summary tabular data.

Summary:

Based on the information provided in this premarket notification, the Glooko Logbook Application, MeterSync Cable and Chart software tool is substantially equivalent to the predicate device and is suitable for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 21, 2012

Glooko, Inc.
c/o Shilpa Mydur
Regulatory Affairs Manager
170A University Avenue
Palo Alto, CA 94301

Re: k122142
Trade/Device Name: Glooko Device System for Logbook Application & Glooko Logbook Charts
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW, JQP
Dated: October 30, 2012
Received: November 2, 2012

Dear Shilpa Mydur,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
In Vitro Diagnostic Devices and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122142

Device Name: Glooko Device System for the Glooko Logbook Application and Glooko Logbook Charts

Indications for Use:
The Glooko device system for the Glooko Logbook Application and Glooko Logbook Charts are data management software intended for use in home and professional settings to aid individuals with diabetes and their health care professionals in review, analysis and evaluation of blood glucose readings to support an effective diabetes management program. The Glooko device system for the Glooko Logbook Application connects to compatible FDA cleared meters and allows users to transfer their blood glucose meter results to their iPhone operating system platform.

The Glooko device system for the Glooko Logbook Application and Glooko Logbook Charts are not intended to provide treatment decisions or to be used as a substitute for professional healthcare advice.

Prescription Use _____ (21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use _x_. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) K122142